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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,904	01/18/2002	Janice Au-Young	PF-0723 USN	8248

27904 7590 06/24/2002

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/24/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,904

Applicant(s)

AU-YOUNG ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1, 2, 16, and 17, drawn to polypeptides and a pharmaceutical composition comprising a polypeptide.
- II. Claims 3-7, 9, 11, and 12, drawn to polynucleotides, host cells, and a method of producing a polypeptide.
- III. Claim 8, drawn to a transgenic organism comprising a recombinant polynucleotide.
- IV. Claim 10, drawn to an antibody.
- V. Claims 13-15, drawn to a method of detecting a target polynucleotide in a sample.
- VI. Claim 18, drawn to a method for treating a disease or condition associated with decreased expression of functional RECAP comprising administering a pharmaceutical composition comprising a polypeptide to a patient.
- VII. Claim 19, drawn to a method for screening a compound for effectiveness as an agonist of a polypeptide.

- VIII. Claims 20 and 21, drawn to a pharmaceutical composition comprising an agonist compound and a method for treating a disease or condition associated with decreased expression of functional RECAP.
- IX. Claim 22, drawn to a method for screening a compound for effectiveness as an antagonist of a polypeptide.
- X. Claims 23 and 24, drawn to a pharmaceutical composition comprising an antagonist compound and a method for treating a disease or condition associated with overexpression of functional RECAP.
- XI. Claim 25, drawn to a method for screening a compound that specifically binds to the polypeptide.
- XII. Claim 26, drawn to a method for screening a compound that modulates the activity of the polypeptide.
- XIII. Claim 27, drawn to a method for screening a compound for effectiveness in altering expression of a target polynucleotide.
- XIV. Claim 28, drawn to a method for assessing toxicity of a test compound.
2. The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XIV appears to be the claimed amino acid/nucleic acid sequences. However, Claims 1, 3-7, 9, 11, and 12 are anticipated by Seol et al. (EMBL database, Accession No. U22015, March, 15, 1995; Seol et al, Mol. Endocrinol. 9(1), 72-85, 1995) or by Strausberg et al. (EMBL database,

Accession No. AI337112, December 31, 1998). The references teach a polypeptide fragment of SEQ ID NO: 1.

Therefore, the technical feature linking the inventions of Groups I-XIV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

3. The special technical feature in Groups I-IV is polypeptides, polynucleotides encoding the polypeptides, a transgenic organism comprising a recombinant polynucleotides, and antibodies against the polypeptides, respectively; the special technical feature in Groups V, VI, VIII, and X is a method of detecting a polynucleotides, and a method for treating a disease or condition associated with decreased expression or overexpression of functional RECAP, respectively; the special technical feature in Groups VII, IX, XI-XIV is a method for screening a compound for effectiveness as an agonist or an antagonist of a polypeptide, a method for screening a compound that specifically binds to a polypeptide or modulates the activity of a polypeptide, a method for screening a compound for effectiveness in altering expression of a target polynucleotides, or a method for assessing toxicity of a test compound. These methods are completely different as evidenced by different method steps and use.
4. Accordingly, Groups I-XIV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.
5. Furthermore, the application contains numerous nucleic acid/amino acid sequences. Each individual sequence represents a structural and functionally distinct entity that is

capable of supporting a separate patent. The search and consideration of more than a single sequence constitutes an undue search burden on the office, given the ever-increasing size of the database.

Applicant is advised that a reply to this requirement must include an identification of an amino acid or nucleic acid sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
June 18, 2002



ELIZABETH KEMMER
PRIMARY EXAMINER